

REMARKS

This Paper is submitted in response to the Office Action mailed September 15, 2005. This Paper is filed within the three-month shortened statutory response period, namely December 15, 2005. The Commissioner is hereby authorized to charge any additional fees to Deposit Account number 02-1818.

Claims 14-18, 23, 25, and 27-29 were rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to provide adequate support in the Specification for the claimed subject matter. Specifically, the Patent Office alleges that the Specification does not appear to provide support Regarding “absorbing at least a portion of the caffeine saliva content through the oral mucosa” in Claim 14, Applicants have replaced the term, “portion” with the term, “amount”. Support for this term can be found in the Specification at, for example, page 9, lines 19-23. Accordingly, Applicants respectfully submit that the rejection has been overcome.

Regarding Claim 23, Applicants respectfully submit that the terms “a first amount of caffeine”, “a second amount of caffeine” and “the first and second amounts of caffeine” are supported in the Specification at, for example, page 8, lines 20-28. It is an axiom of patent law that the claims do not require *ipsis verbis* support. *In re Wertheim*, 191 USPQ 90, 96 (CCPA 1976). Applicants respectfully submit that the skilled artisan would understand that the specification discloses a first amount of caffeine is enterally ingested (i.e. “ingested orally,” page 8, line 23) followed by buccal absorption of a second amount of caffeine (“chewing gum with caffeine...create[s] a synergistic effect with...caffeine...in systemic circulation,” page 8, lines 25-27). Therefore, the Specification adequately discloses enterally ingesting caffeine to provide a first amount of caffeine in the systemic system, chewing a chewing gum that contains caffeine, causing a second amount of caffeine to be released by the chewing gum, and the first and second amounts of caffeine providing an effective amount of caffeine in the systemic system as recited in Claim 23. Accordingly, Applicants respectfully submit that the rejection should be withdrawn.

Regarding the phrases “adjusting the hydrophilic/lipophilic balance of the stimulant” in Claim 27, “blending the stimulant with a base/emulsifier system” in Claim 28, and “the blending occurs before the providing” in Claim 29, Applicants respectfully submit that the Specification provides support at, for example, page 13, line 30 through page 14, line 10. The skilled artisan

would readily acknowledge that the Specification discloses that the hydrophilic/lipophilic balance may be adjusted based on the water solubility of the medicament. Additionally, the Specification provides at page 14, lines 6-7 that "the smaller the amount of active ingredient used, the more necessary it becomes to preblend that particular ingredient." Therefore, the Specification adequately discloses "adjusting the hydrophilic/lipophilic balance of the stimulant" as recited in Claim 27, "blending the stimulant with a base/emulsifier system" as recited in Claim 28, and "the blending occurs before the providing" as in Claim 29. Accordingly, Applicants respectfully submit that the rejection should be withdrawn.

Claims 7, 8, 10-12, and 27-29 were rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. Regarding the term " enteral administration amount" in Claim 7, it is a further axiom of patent law that all words in a claim must be considered in determining patentability. *In re Wilson*, 165 USPQ 894, 196 (CCPA 1970). When properly interpreting Claim 7, it is clear that Claim 7 recites that the enteral administration amount corresponds to an effective amount of stimulant. As enteral administration of drugs is, by far, the most common drug delivery practice, one of ordinary skill in the art would readily understand what enteral dosage amount is necessary to deliver an effective amount of a given stimulant. *See for example*, the Specification at page 2, lines 11 to 17. Moreover, the art is replete with references and indices that set forth enteral dosage amounts for delivering an effective amount of a drug or stimulant. *See for example, The Physician's Desk Reference*. As Claim 7 clearly recites that the enteral administration amount corresponds to the stimulant effective amount, and the enteral amount required to deliver an effective amount of stimulant is well within the capacity of the skilled artisan, Applicants respectfully submit that Claim 7 is fully supported by the Specification and thereby definite. Accordingly, Applicants respectfully submit that the rejection of Claims 7, 8, and 10-12 should be withdrawn.

Claims 27-29 were also rejected under 35 U.S.C. §112, second paragraph, for allegedly being in improper dependent form. In response, Applicants have amended Claims 27 and 28 to refer to "providing a chewing gum" in Claim 7 to recite additional features of the chewing gum provided in Claim 7. In addition, Applicants have amended Claim 29 to be dependent on Claim 28 to provide sufficient antecedent basis. Therefore, the claims comply with 35 U.S.C. 112, second paragraph, and such rejection should be withdrawn.

Claims 7, 8, 10-12, 14-18, 23, 25 and 26 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,586,023 to Song et al. (“*Song*”). Claims 7, 8, 10-12, 14-18, 23, 25 and 26 were also rejected under 35 U.S.C. §103(a) as being unpatentable over PCT Application No. WO 98/23165 to Gudas et al. (“*Gudas*”). Applicants respectfully disagree with and traverse these rejections for the reasons set forth below.

The present application, Application Serial Number 10/743,609, and *Song*, were, at the time the invention of Application Serial Number 10/743,609 was made, owned by Wm. Wrigley Jr. Company or subject to an obligation of assignment that would establish common ownership by Wm. Wrigley Jr. Company. Therefore, in accordance with 35 U.S.C. §103(c), Applicants respectfully submit that *Song* should be removed as a reference, and that this rejection should be withdrawn.

Gudas does not teach or suggest a method for reducing the amount of stimulant necessary to deliver an effective amount of the stimulant to an individual as in Claim 7. Rather, *Gudas* merely discloses a gum containing physically modified caffeine that controls the rate of release from the gum. Nowhere does *Gudas* disclose or suggest reducing the amount of stimulant necessary to deliver an effective amount of the stimulant to an individual as in Claim 7. Consequently, *Gudas* does not disclose or suggest anything related to providing gum with less than an effective enteral amount. Therefore, Applicants respectfully submit that the rejection of Claim 7 and the claims which depend therefrom should be withdrawn.

Also, *Gudas* does not teach or suggest enhancing an individual's performance by, among other elements, providing a chewing gum including a performance enhancing amount of caffeine to be adsorbed through the oral mucosa of the individual as in Claim 14. In contrast, the object of *Gudas*' physically-modified gum is to deliver and mask bitter tasting caffeine as it is released to a person's digestive tract. *Gudas*, page 5, lines 1-4. Regardless of whether the caffeine is modified to be quickly ingested or slowly ingested into the digestive tract of the chewer, the physical modification of caffeine would inhibit absorption of the caffeine across the oral mucosa in the buccal cavity in complete contrast to the claimed invention. *Gudas*, page 11, lines 21-25. As *Gudas* discloses releasing caffeine to a person's digestive tract, *Gudas* does not teach or suggest absorbing caffeine through the oral mucosa of the individual as in Claim 14.

Furthermore, nowhere in *Gudas* is there any hint or suggestion of a method of increasing the stimulatory effect of caffeine that includes enterally ingesting caffeine and also chewing caffeine-containing gum to force caffeine through the oral mucosa as in Claim 23. Accordingly, Applicants respectfully submit that the obviousness rejection should be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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